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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GODDARD, LAURA B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,755	ROMET-LEMONNE ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-59* is/are pending in the application.

4a) Of the above claim(s) *46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-45 and 47-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed August 19, 2005 in response to the Office Action of April 19, 2005 is acknowledged and has been entered. Applicants elected without traverse Group I (claims 1-14, 40) and tumor associated antigen. Group I is drawn to a method of stimulating an immune response comprising administering a binding agent and an antigen. Applicants cancelled claims 1-40 and added claims 41-59 which are drawn to a method of enhancing presentation of an antigen to an immune cell in a subject and a method for targeting an antigen to an antigen-presenting cell which invention is supported by the original claims of Group 1. Claim 46 and limitations of claims 45 and 59 drawn to antigens other than tumor associated antigens have been withdrawn from further consideration by the examiner under 35 CFR 1.142(b) as being drawn to non-elected inventions. Claims 41-45 and 47-59 are currently under prosecution.

Specification

2. The specification is objected to for the following reason: The specification on page 1 should be amended to reflect the most current priority status of the present application, including proper reference to applications that have been issued or abandoned.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The term "**tumor-associated antigen**" in claims 45 and 59 is a relative term which renders the claim indefinite. The term " **tumor-associated antigen** " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Given the above reasons, the metes and bounds of the claims cannot be determined.

4. Claims 41 and 52 recite the limitation "the receptor". There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 41 and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A WRITTEN DECRIPTION REJECTION.

The claims are drawn to a method of enhancing presentation of an antigen to an immune cell in a subject comprising administering said antigen linked to a binding **agent** which binds to FcγRI. The specification discloses binding agents as a heteroantibody, bispecific antibody, or other bispecific molecule having a binding specificity for the antigen and a binding specificity for a surface receptor of an antigen-presenting cell (p. 2). The specification discloses preferred binding agents to include antibodies specific for various antigens and antibodies that recognize the FcγRI receptor (p. 5). The specification only teaches and exemplifies an antibody as a binding agent in pages 12-15 and Examples 1-3, respectively. The specification does not disclose any other agents as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. There is no identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the

application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the binding agent which binds to FcγRI on an antigen-presenting cell, per Lilly by structurally describing representative agents or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe a binding agent which binds to FcγRI on an antigen-presenting cell in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses antibodies as binding agents, this does not provide a description of the broadly claimed binding agents that would satisfy the standard set out in Enzo because the specification provides no functional characteristics coupled to structural features.

Further, the specification also fails to describe a binding agent which binds to FcγRI on an antigen-presenting cell by the test set out in Lilly because the specification describes only antibodies. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of a method of enhancing presentation of an antigen to an immune cell in a subject comprising administering said antigen linked to a binding agent which binds to FcγRI that is required to practice the claimed invention. Since the specification fails to adequately describe the binding agent, it also fails to adequately describe the method of enhancing presentation of an antigen to an immune cell in a subject.

Note: If applicant were to overcome the preceding rejection (s) under 35 U.S.C. 112, first paragraph, the following claims would still be rejected under 35 U.S.C. 112, first paragraph, scope of enablement:

6. Claims 41-45, and 47-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **a method of enhancing presentation of an antigen to an immune cell in cell culture (*in vitro*)**, does not reasonably provide enablement for **a method of enhancing presentation of an antigen to an immune cell in a subject (*in vivo*)**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a method of enhancing presentation of an antigen to an immune cell in a subject. The specification teaches that the compositions of this invention can be used to treat tumors (p. 6) that the complex may be used to raise an immune response for treatment of tumors (p. 18). In particular, the specification teaches that the agent can be used to target a tumor-associated (or tumor-specific) antigen to an antigen-presenting cell in order to cause or to enhance an immune response against the tumor (p. 20). The specification exemplifies a method of enhancing presentation of an antigen to an immune cell in cell culture (Example 2).

One cannot extrapolate the teaching of the specification to the scope of the claims because said teachings represent insufficient guidance and objective evidence to predictably enable the use of the claimed invention. Thus, the claims are not enabled for a method of enhancing presentation of an antigen to an immune cell in a subject (*in vivo*). Those of skill in the art recognize that *in vitro* assays and or cell-cultured based assays are generally useful to observe basic physiological and cellular phenomenon such as screening the effects of potential drugs. However, clinical correlations are generally lacking. The greatly increased complexity of the *in vivo* environment as compared to the very narrowly defined and controlled conditions of an *in vitro* assay does not permit a single extrapolation of *in vitro* assays to human diagnostic efficacy with any reasonable degree of predictability. *In vitro* assays cannot easily assess cell-cell interactions that may be important in a particular pathological state.

In particular, it is well known in the art that cultured cells, over a period time, lose phenotypic characteristics associated with their normal counterpart cell type. Freshney

(Culture of Animal Cells, A Manual of Basic Technique, Alan R. Liss, Inc., 1983, New York, p4) teach that it is recognized in the art that there are many differences between cultured cells and their counterparts *in vivo*. These differences stem from the dissociation of cells from a three-dimensional geometry and their propagation on a two-dimensional substrate. Specific cell interactions characteristic of histology of the tissue are lost. The culture environment lacks the input of the nervous and endocrine systems involved in homeostatic regulation *in vivo*. Without this control, cellular metabolism may be more constant *in vitro* but may not be truly representative of the tissue from which the cells were derived. This has often led to tissue culture being regarded in a rather skeptical light (p. 4, see Major Differences In Vitro). Further, Dermer (Bio/Technology, 1994, 12:320) teaches that, petri dish cancer" is a poor representation of malignancy, with characteristics profoundly different from the human disease. Dermer teaches that when a normal or malignant body cell adapts to immortal life in culture, it takes an evolutionary type step that enables the new line to thrive in its artificial environment. This step transforms a cell from one that is stable and differentiated to one that is not. Yet normal or malignant cells *in vivo* are not like that. The reference states that evidence of the contradictions between life on the bottom of a lab dish and in the body has been in the scientific literature for more than 30 years. Clearly it is well known in the art that cells in culture exhibit characteristics different from those *in vivo* and cannot duplicate the complex conditions of the *in vivo* environment involved in cell-cell interactions or immune responses.

Further, the treatment of cancer is both contemplated and claimed by inference because of the targeting of the complex to tumor-associated antigen. Given that the teachings of the specification and the claims are clearly drawn to using the claimed method in the treatment of diseases including cancer, the teachings of Gura (Science, 1997, 278:1041-1042), Jain (Sci. Am., 1994, 271:58-65), and Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) are particularly relevant to the instant rejection.

Gura teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that a compound capable of modulating cellular proliferation could be predictably used as an anti-cancer agent for cancer therapeutic strategies as inferred by the claim and as contemplated by the specification. Further, the refractory nature of cancer to drugs is well known in the art. Jain teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti teaches that solid tumors resist destruction by chemotherapy agents and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of

patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the invention will function as inferred, contemplated, and claimed based only on *in vitro* experiments as disclosed in the specification. In addition, anti-tumor agents must accomplish several tasks to be effective. They must be delivered into the circulation that supplies the tumor and interact at the proper site of action and must do so at a sufficient concentration and for a sufficient period of time.

Also, the target cell must not have an alternate means of survival despite action at the proper site for the drug. In addition variables such as biological stability, half-life or clearance from the blood are important parameters in achieving successful therapy. The agent may be inactivated *in vivo* before producing a sufficient effect, for example, by degradation, immunological activation or due to an inherently short half-life of the agent. In addition, the agent may not otherwise reach the target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the agent has no effect, circulation into the target area may be insufficient to carry the agent and a large enough local concentration may not be established. Reasonable correlation must exist between the scope of the claims and

scope of enablement set forth, and it cannot be reasonably predicted that the invention will predictably function as inferred, contemplated, and claimed based only on *in vitro* experiments as disclosed in the specification.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be reasonably predicted that a method of enhancing presentation of an antigen to an immune cell in a subject will predictably function as disclosed. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the claimed invention of a method of enhancing presentation of an antigen to an immune cell in a subject would function as contemplated by the specification with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 42 and 53 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 14, respectively of prior U.S. Patent No. 6,258,358. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 41, 43-45, 47-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8-13 of U.S. Patent No. 6,258,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the application are claiming common subject matter.

The claims of the instant application are drawn to a method of enhancing presentation of an antigen to an immune cell in a subject comprising administering to the subject an antigen linked to a binding agent which binds to FcγRI on an antigen-presenting cell (APC) (claim 41), wherein the antigen is covalently crosslinked to the

binding agent (claim 43), wherein the binding agent comprises a bispecific antibody or heteroantibody having affinity for FcγRI and for the antigen (claim 44) wherein the antigen is a tumor-associated antigen (claim 45), wherein the APC is a macrophage, monocyte or dendritic cell (claim 47), wherein the complex comprises a first antibody that specifically binds to FcγRI without prevention by IgG and a second antibody which specifically binds the antigen (claim 48), wherein the complex comprises an Fab-Fab conjugate (claim 49), wherein the complex comprises a fusion protein comprising an antibody and the antigen (claim 50), and wherein the complex is produced recombinantly (claim 51).

Similarly, the claims of the patent are drawn to a method of enhancing presentation of an antigen to an immune cell in a subject comprising administering to the subject an antigen linked to an antibody which binds to FcγRI on an APC (claim 1), wherein the antigen is covalently crosslinked to the antibody (claim 2), wherein the antibody is a bispecific antibody having binding affinity for FcγRI and for the antigen (claim 3), wherein the antibody is a heteroantibody (claim 4), wherein the antigen is a tumor-associated antigen (claims 5 and 8), wherein the APC is a macrophage, monocyte or dendritic cell (claim 9), wherein the complex comprises a first antibody that specifically binds to FcγRI without prevention by IgG and a second antibody which specifically binds the antigen (claim 10), wherein the complex comprises an Fab-Fab conjugate (claim 11), wherein the complex comprises a fusion protein comprising an antibody and the antigen (claim 12), and wherein the complex is produced recombinantly (claim 13).

This means that claims 1-5, 8-13 of the patent and claims 41, 43-45, 47-51 of the instant application are drawn to the same subject matter, excepting that claims 1-5, 8-13 are drawn to a binding agent which is an antibody and thus is a species of the instantly claimed invention.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have substituted an antibody for the binding agent of the instant invention because antibodies are well-known and conventional binding agents in the art.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5, 8-13 of the patent are drawn to a species of the instant invention of claims 41, 43-45, 47-51 and therefore claims 1-5, 8-13 of the patent make obvious the instantly claimed invention which is generic to the species of claims 1-5, 8-13.

9. Claims 52 and 54-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-20 of U.S. Patent No. 6,258,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent and the application are claiming common subject matter.

The claims of the instant application are drawn to a method for targeting an antigen to an APC comprising contacting the APC with a binding agent which binds to

FcγRI on an APC and an antigen targeted to the FcγRI receptor on the APC (claim 52), wherein the APC is a macrophage, monocyte or dendritic cell (claim 54), wherein the binding agent comprises a bispecific antibody or heteroantibody (claim 55), wherein the antigen is covalently crosslinked to the binding agent (claim 56), wherein the complex comprises a fusion protein comprising an antibody and the antigen (claim 57), wherein the complex is produced recombinantly (claim 58), and wherein the antigen is a tumor-associated antigen (claim 59).

Similarly, the claims of the patent are drawn to a method for targeting an antigen to an APC comprising contacting the APC with an antibody which binds to FcγRI on an APC and an antigen targeted to the FcγRI receptor on the APC (claim 14), wherein the APC is a macrophage, monocyte or dendritic cell (claim 15), wherein the antibody is a bispecific antibody (claim 16), wherein the antigen is covalently crosslinked to the binding agent (claim 17), wherein the complex comprises a fusion protein comprising an antibody and the antigen (claim 18), wherein the antigen is Her2/neu (claim 19), and wherein the complex is produced recombinantly (claim 20). It is noted that the specification of the patent specifically defines Her2/neu as a tumor associated antigen (col. 7, lines 35-39). It is further noted that the MPEP 2111.01, in part, states that when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970).

This means that claims 14-20 of the patent and claims 52-59 of the instant application are drawn to the same subject matter, excepting that claims 14-20 are

drawn to a binding agent which is an antibody and thus is a species of the instantly claimed invention, and claim 19 is drawn to Her2/neu antigen which is a species of tumor-associated antigen.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have substituted an antibody for the binding agent of the instant invention because antibodies are well-known and conventional binding agents in the art. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have substituted the tumor-associated Her2/neu antigen for the tumor-associated antigen of the instant invention because Her2/neu is a well-known tumor-associated antigen as defined by the specification of the patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14-20 of the patent are drawn to a species of the instant invention of claims 52-59 and therefore claims 14-20 of the patent make obvious the instantly claimed invention which is generic to the species of claims 14-20.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

George C. Elliott, Ph.D
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